

**Evaluation of the Region 2  
Drinking Water Laboratory Certification Program**

**by the**

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**Office of Ground Water and Drinking Water  
Technical Support Center**

**September 24, 2012**

**U. S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Water  
Office of Ground Water and Drinking Water  
Standards and Risk Measurement Division  
Technical Support Center  
Cincinnati, Ohio 45268**

## Introduction

The “Manual for the Certification of Laboratories Analyzing Drinking Water” requires the Office of Ground Water and Drinking Water (OGWDW) to “review the Regional drinking water certification programs annually and evaluate the resources and personnel available in each Region to carry out the certification program.” Paper reviews in the form of questionnaires are done annually with on-site reviews conducted triennially. The on-site audits and evaluations are conducted in order to assess the adherence of the EPA Regional Certification Authority to the requirements of the “Manual for the Certification of Laboratories Analyzing Drinking Water,” Chapters I – III, Fifth Edition, EPA 815-R-05-004, 2005 (MCLADW or “the manual”).

The Region 2 Laboratory Certification Program (LCP) resides in the Region 2 Division of Environmental Science and Assessment, Monitoring and Assessment Branch, Air and Water Quality Assurance Team, located at the Region 2 Edison Environmental Center in Edison, NJ. Deb Szaro is the director of the Environmental Science and Assessment Division, John Kushwara is the chief of the Monitoring and Assessment Branch, Carol Lynes is the leader of the Air and Water Quality Assurance Team, which is responsible for the implementation of the Region 2 LCP. Donna Ringel, a member of the Air and Water Quality Assurance team, serves as the Region 2 Laboratory Certification Program Manager (LCPM). Other individuals of the Region 2 staff that participate in the laboratory certification program as certification officers (COs) are as follows: Deborah Kay (Microbiology CO), Ness Tirol (Inorganic/Organic Chemistry CO), and Sumy Cherukara (Inorganic/Organic Chemistry CO). See Attachment 1 for an organizational chart of the Region 2 LCP.

Jennifer Best, Judy Brisbin, and Dan Hautman of the Technical Support Center (TSC) performed an on-site review of the Region 2 Drinking Water LCP on May 8 – 10, 2012, at the Region 2 Edison Environmental Center in Edison, NJ. An entrance conference was held on May 8, and those in attendance were: Jennifer Best, Judy Brisbin, Dan Hautman, Donna Ringel, Carol Lynes, and John Kushwara. See Attachment 2 for the Agenda from the TSC audit of Region 2 LCP.

The audit of the Region 2 LCP included a review of Region 2 files for all state and territory Principle State Laboratories (PSLs) certified by the Region, along with the regional oversight of the drinking water LCPs coordinated in each state and territory within the Region. In addition to the review of the files, the TSC auditors discussed with Ms. Ringel issues of concern within the Region 2 LCP. The Region 2 staff was cooperative and helpful to the TSC auditors and quickly supplied any requested documentation. (Note: Hereafter, unless otherwise clarified, all general references to “state” or “states” within Region 2 refer to the primacy agencies of both states and territories).

On May 9, 2012, Region 2 held a meeting with the states, addressing a variety of drinking water topics. TSC participated in this meeting by giving a presentation entitled “Drinking Water Update”. See Attachment 3 for the agenda from the Region 2 Drinking Water meeting. There were participants from every state in Region 2 at this meeting (NJ, NY, VI, and PR), along with several individuals from Region 2. The meeting was concurrently broadcast as a web-

conference, with remote participants participating via internet. See Attachment 4 for a complete list of all meeting participants.

At the conclusion of the audit, an exit debrief meeting was held on May 10, 2012. Attendees at this meeting included: Jennifer Best, Judy Brisbin, Dan Hautman, Deb Szaro, Kevin Kubik (Deputy Director, Division of Environmental Science and Assessment/Regional Science Advisor), John Kushwara, Carol Lynes, and Donna Ringel. At this meeting, findings from the audit were discussed as well as other laboratory certification topics.

### **Quality and Timeliness of State Laboratory Audits**

Regional audits of PSLs are to be conducted on a 3-year cycle as described in the manual. Along with PSL audits, on-site assessments of the state laboratory certification programs should be performed on a triennial basis, as outlined in Chapter III of the manual. The chart below lists the most recent dates of the onsite audits of the PSL state/territory laboratories and assessments of the state/territory drinking water laboratory certification programs for Region 2. Donna Ringel participated as a part of The NELAC Institute (TNI) evaluation team for the National Environmental Laboratory Accreditation Program (NELAP) Accreditation Body (AB) audits of New Jersey and New York.



	<p>National Testing Laboratories (NTL) (Commercial Lab) (Ypsilanti, MI)</p> <p>Pace Analytical Services, Inc. (Pace) (Commercial Lab) (Pittsburgh, PA)</p>		<p>LA DEQ (TNI) May 2012</p> <p>-----</p>	<p>-----</p> <p>-----</p>	<p>-----</p> <p>PA (TNI) PA-DEP/July 2011</p>
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All of the PSL audits and LCP reviews are current in Region 2. Prior to this audit, the audits of the New Jersey chemistry, microbiology, and radiochemistry laboratories were behind schedule due to a pending move to a new facility that was delayed several times over a period of several years. However, the laboratory has now relocated and Region 2 recently completed these audits making Region 2 current for all PSLs.

Region 2 does not conduct independent on-site assessments of the PSL for state laboratories accredited by a recognized NELAP AB. For those PSLs, Region 2 uses the NELAP accreditation as a basis for EPA drinking water laboratory certification. Region 2 then issues a letter to the PSL recognizing the NELAP accreditation. Ms. Ringel does participate in the laboratory audits through participation in the exit debrief meetings, for which she is to be commended. Participation by Region 2 in the exit debrief meetings allows Region 2 to understand the laboratory's deficiencies and how corrective actions and follow up will be handled by the laboratory and the Accrediting Body.

Region 2 has a Standard Operating Procedure (SOP) entitled "Drinking Water Laboratory Certification Program Procedures," which provides an overview of how the Region 2 LCP is operated. While this document indicates that Region 2 conducts triennial on-site assessments of the certified laboratories, it does not describe in detail how Region 2 conducts laboratory audits. The TSC audit team recommends that Region 2 prepare a more detailed SOP describing how the laboratory audits are conducted. Such a document will serve to ensure that all of the audits conducted by Region 2 are performed consistently.

### **Reviews of State Certification Programs**

On an annual basis, TSC sends a questionnaire to all of the Regional LCPMs regarding the status of the certification program in the states within their Region, which the Region then forwards onto the states for completion. This questionnaire serves as an annual program review for the states in Region 2, while on-site evaluations of the state programs, conducted by Ms. Ringel, occur on a triennial basis. As with the on-site laboratory audits, Region 2 has been diligent in ensuring the on-site LCP reviews are conducted every three years.

Region 2 has been actively participating in the TNI review of the NY and NJ TNI-based laboratory accreditation programs. The TSC audit team noted that Ms. Ringel fully participated in the evaluation panels, and the evaluations were complete, with all drinking water concerns addressed.

In addition to participating in the TNI AB reviews, Region 2 oversees the NJ certification program (NJ runs both accreditation and certification programs) along with the PR and VI LCPs. The Region 2 review of the NJ LCP in June 2009 identified important vulnerabilities (i.e. no SOPs are prepared/used, PTs being tracked by technique, not method). The TSC audit team, commends Region 2 for identifying these deviations, and supports Region 2's efforts to improve the NJ their certification program.

As noted in the Region 2 report, many of the NJ COs completed the OGWDW CO Training Course many years ago but have not returned for refresher training. A cursory review by the

TSC audit team found that NJ has 10 chemistry COs in need of attending the refresher training (for six of these individuals it has been over ten years since they have attended the CO training course). In addressing this problem, the TSC audit team notes that Region 2 has offered to host the training course at the Edison facility in 2013 and has received confirmation from NJ LCP management that they will send the COs to the course if it is held at the Region 2 facility. At the time of this report, TSC anticipates working with Region 2 to conduct the training at the Edison facility in 2013.

The TSC audit team notes that in the most recent LCP reviews for both PR and VI, Region 2 identified important vulnerabilities for these programs, with many of the PR findings found as repeat findings. The TSC audit team commends Region 2 for identifying the deficiencies within the programs, and encourages Region 2 to ensure the programs follow up and implement the Region 2 corrective actions/suggestions in order to make the LCPs in these areas stronger.

### **Regional Certification Program Files**

The OGWDW evaluation team reviewed files from the four states and territories within Region 2. We found Region 2 to have organized files for each of the states. The TSC audit team noted that Ms. Ringel had included her audit notes in the files, and commends Region 2 for this practice, as it allows future evaluation teams to be more thoroughly prepared for up-coming audits. The TSC audit team encourages Region 2 to also include the CO notes in the audit files so that the notes could be referenced, if necessary.

The TSC audit team noted that Region 2 was diligent in following up with the contract laboratories used by Puerto Rico and the Virgin Islands for analyses that they do not have in-house (i.e., some chemistry and radiochemistry analyses). Region 2 tracks which laboratories the territories are using, and the certification status of the contracted laboratories, a process worthy of commendation.

In the previous TSC audit report, our office recommended that Region 2 include in their files any relevant correspondence with state counterparts to ensure the file completeness. During this audit, the TSC audit team found that Region 2 had followed this recommendation, and began to include technical communication with the states/territories in the files. As a result, the files are more complete, and it is evident from reviewing the files that clear lines of communication exist with the states and territories reflecting good relationships with these programs, which contributes to a strong LCP for Region 2 and their states/territories.

### **Communications with State Counterparts**

Region 2 held a triennial meeting on May 9, 2012, in conjunction with the TSC program review (Attachment 2). The meeting was well organized and attended by several representatives from the PSLs and certification programs of New York, US Virgin Islands, Puerto Rico and New Jersey, as well as many Region 2 employees. Region 2 is to be commended for putting together an agenda of interesting, relevant topics that stimulated discussion and interaction by the attendees.

Given the high level of attendance and the amount of discussion amongst the states/territories and Ms. Ringel, it is evident that Region 2 has good relationships with the LCP personnel from all of the states/territories in the Region. This is further evidenced by a recent situation that arose in a Region 2 state whereby a state PSL was failing Proficiency Tests (PTs). Ms. Ringel coordinated a conference call between technical staff in the Region 2 laboratory, TSC personnel, and state personnel to attempt to figure out the root cause of their problems. In addition, at the Region 2 meeting, Ms. Ringel facilitated networking between personnel from the affected laboratory and their counterparts at a neighboring state laboratory. This networking initiated a conversation about the problems the lab was experiencing and the neighboring state's laboratory personnel offered further technical assistance.

Through the years, Region 2 has had many challenging situations arise among the states within the Region. Region 2, in particular, Ms. Ringel, has skillfully and diplomatically dealt with difficult personalities, politically challenging situations, and cultural differences. The TSC audit team believes that due to Ms. Ringel's commitment to cooperative forward progress, she has served as catalyst to convert sometimes adversarial relationships into productive partnerships earning the respect of all of the state/territory LCPs within Region 2. Region 2, in particular Ms. Ringel, are to be commended for developing and nurturing these relationships as these efforts serve to protect public health by ensuring a strong LCP in these states and territories.

## **Resources**

Region 2 continues to adequately support the drinking water LCP through both personnel and travel resources. Ms. Ringel runs the programmatic aspects of the LCP, and utilizes Region 2 Laboratory personnel as the COs for the laboratory audits. Other individuals of the Region 2 Laboratory staff that participate in the LCP as certification officers (COs) are as follows: Deborah Kay (Microbiology CO), Ness Tirol (Inorganic/Organic Chemistry CO), and Sumy Cherukara (Inorganic/Organic Chemistry CO). Hiep Tran has completed the *Cryptosporidium* Certification Officer training course.

The Region 2 COs have all successfully completed Drinking Water Laboratory CO training course for either Microbiology or Chemistry. MCLADW recommends (5<sup>th</sup> Edition, page III-9, 17): "Certification officers should attend refresher training programs at least every five years to keep their knowledge of the methods and the drinking water program current." Mr. Tirol completed the Inorganic/Organic Chemistry course in 2002, and this is due to complete refresher training for the course. Additionally, it is recommended that all individuals that participate in the *Cryptosporidium* CO training course first complete either the Drinking Water Laboratory Certification Officer training course for either Microbiology or Chemistry. Therefore, the TSC audit team recommends that Mr. Tran complete either of these courses in order for him to have a more complete understanding of the National Primary Drinking Water Regulation structure, which is not covered in the *Cryptosporidium* course.

**FINDINGS:**

- None

**RECOMMENDATIONS:**

- Prepare SOP for describing specific protocol for how Region 2 conducts PSL laboratory audits.
- Ensure COs participate in refresher training as necessary.
- Follow up with state/territories to ensure findings and recommendations from the LCP reviews are being appropriately addressed, and corrective actions are being instituted.

Submitted September 24, 2012

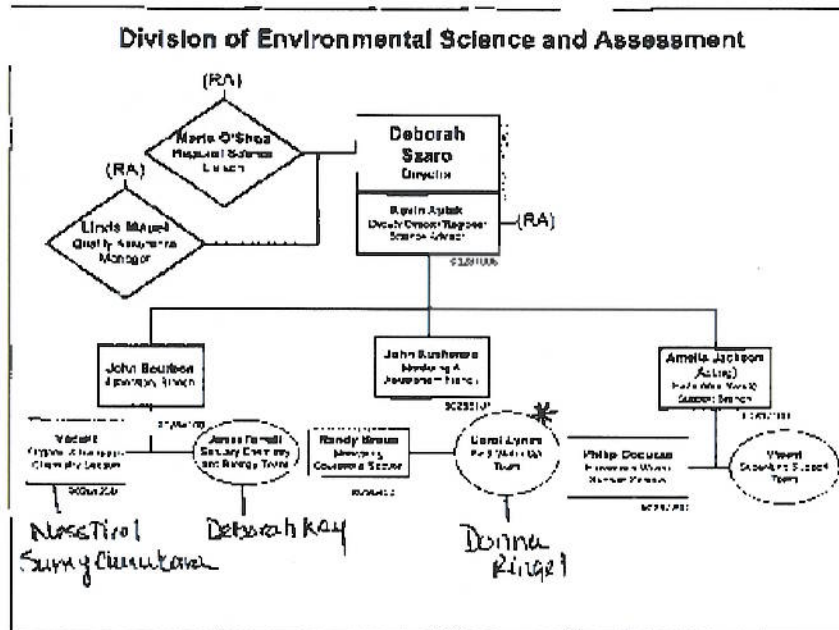
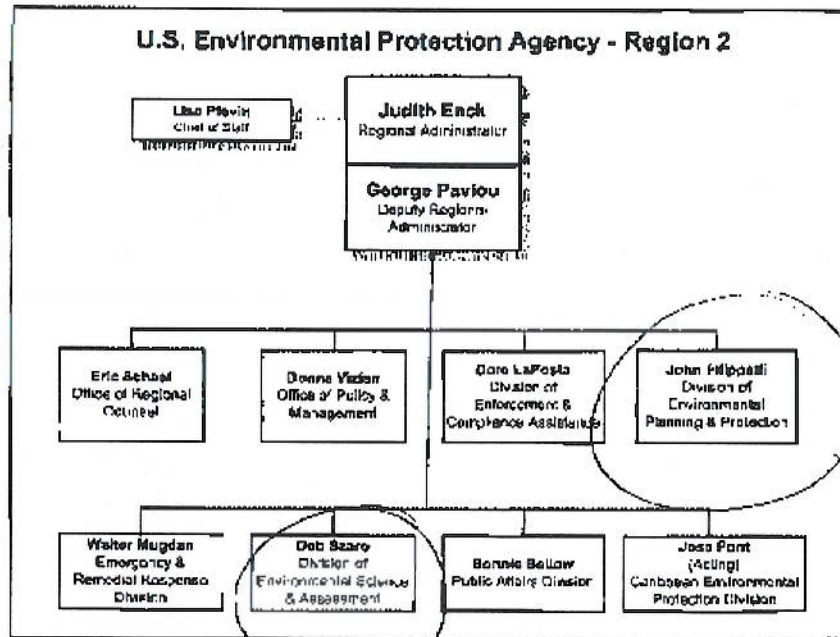
Jennifer M. Best

Jennifer M. Best, OGWDW, TSC

Judith A. Brisbin

Judith A. Brisbin, Ph.D., OGWDW, TSC

# Attachment 1: Region 2 Organizational Chart



ATTACHMENT 2: Agenda of Region 2 Laboratory Certification Program Assessment  
May 8 -10, 2012

**Draft Agenda**

**Region 2 Laboratory Certification Program Audit**

**Tuesday May 8**

9:00 am: TSC arrive at Region 2 lab

10:00 am – ? review of files/discussion of Region 2 laboratory certification program

**Wednesday May 9**

9:00 am: TSC arrive at Region 2 lab

10:30 am: Region 2 Drinking Water/Laboratory Certification Officer meeting

2:30 pm: wrap up of Region 2 DW/LCO meeting

3:00 pm - ? : TSC continue with file review

**Thursday May 10**

9:30 am: TSC arrive at Region 2 laboratory

10:00 am: Jennifer/Judy to tour Region 2 lab facilities as potential certification officer training course facilities

11:00 am: Meet with Region 2 management regarding conducting the laboratory certification officer training at the Region 2 laboratory in 2013

- discuss timeframe for such event
- discuss facility needs (large conference room/auditorium with computer/data projector, ~4-5 laboratories for mock laboratory evaluation exercise, will need micro lab facilities available to prep cultures/media for course w/ weekend access)
- discuss logistical support (signing course attendees in/out every day, lunch?, chemists and microbiologists needed to help in mock laboratory and possibly help with presentations?)
- Can the Cryptosporidium course be taught at the Region 2 lab? (need: analysts, microscopes, prep all stages of method)

1:00 pm: debrief Region 2 laboratory certification team/management (this could possibly be done following the 11:00 meeting, as time/schedules permit)

2:00 pm: TSC depart for airport (4:45 pm flight)

ATTACHMENT 3: Agenda from Region 2 Drinking Water Certification and Quality Assurance  
Officers Meeting, May 9, 2012

U.S. EPA Region 2  
Drinking Water Certification and Quality Assurance Officers Meeting

May 9, 2012  
Agenda

	10:30 am	Welcome and Introductions
10:45 am		Office of Ground Water and Drinking Water Technical Support Center Updates
	12:30 pm	Lunch*
	1:30 pm	Method Update Rule
	2:00 pm	State Certification Program Updates
	2:30	Open Discussion and Questions/Answers

\*Lunch will be provided at the cost of \$10 per person or participants may choose to bring their own brown bag lunch. Catered lunch includes a variety of sandwiches (including roasted veggie wraps), pasta and potato salads, beverage and cookie.

**ATTACHMENT 4: Participants at Region 2 Drinking Water Certification and Quality Assurance Officers Meeting, May 9, 2012**

**Regional Drinking Water Certification Officer and Quality Assurance Officer Meeting  
May 9, 2012**

**Edison, New Jersey – Bldg. 205 Main Conference Room**

Name	Organization	Webinar	In-Person	Lunch	Paid
Nichole Carins	NYSDOH		X	X	
Denise Dubois	NYSDOH		X	X	
Michael Kitto	NYSDOH	X			
Tony Bucciferro	NYSDOH		X	X	
Ellen Braun-Howland	NYSDOH		X		
Min Sook Kim	NYSDOH	X			
Richard Biega	NYSDOH		X	X	
Joan Fleaser	NYSDOH		X	X	
Anne Sheehan	NYSDOH	X			
Diana Shannon	NYSDOH		X	X	
Lynn McNaughton	NYSDOH		X	X	
Daniel Dickinson	BYSDOH	X			
Victoria Pretti	NYSDOH		X	X	
Deborah Kay	EPA		X	X	
Ness Tirol	EPA		X		
Kelly Kinder	EPA		X	X	
Carol Lynes	EPA	X			
Sumy Cherukara	EPA		X	X	
Jennifer Best	EPA		X	X	
Judy Brisbin	EPA		X	X	
Dan Hautman	EPA		X	X	
Donna Ringel	EPA		X	X	
John Kushwara	EPA		X	X	
Jerry McKenna	EPA		X	X	
Esther Nelson	EPA		X	X	
Roseann Garry	NYSDEC	X			
Jason Fagel	NYSDEC	X			
Amy Dempsey	OSL		X	X	
Monica Higdeon	OSL		X	X	
Alex Walls	OSL		X	X	
Martha Smith	NJDHSS		X	X	
Mary Dillon	NJDHSS		X	X	
Sharon Robinson	NJDHSS		X	X	
Shawn Lee	NJDHSS		X	X	

Paul Steitz	NJDHSS		X	X	
Julian Trexler	NJDHSS	X			
Doug Haltmeier	NJDHSS	X			
Bahman Parsa	NJDHSS	X			
Melba Aviles	PRDOH	X			
Nancy Sanchez	PRDOH	X			
Norma Rivera	PRDOH	X			
Gissel Rodriguez	PRDOH	X			
Nadalie Joesph	VIDPNR	X			
Peter Boughton	NJDEP	X			
Stuart Nagourny	NJDEP		X	X	
Bernie Wilk	NJDEP		X		
Amy Bowman	NJDEP		X	X	
Rachel Ellis	NJDEP		X	X	
Paula Blaze	NJDEP		X	X	
Robert Royce	NJDEP		X	X	
Marty Hackman	NJDEP		X		
Linda Bonnette	NJDEP		X	X	